



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,335	12/12/2003	Doddable L. Madhavi	BIO 2-016	3791
266	7590	07/11/2008	EXAMINER	
MUELLER AND SMITH, LPA MUELLER-SMITH BUILDING 7700 RIVERS EDGE DRIVE COLUMBUS, OH 43235				MAIER, LEIGH C
ART UNIT		PAPER NUMBER		
1623				
			MAIL DATE	DELIVERY MODE
			07/11/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/735,335	MADHAVI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 April 2008 and 21 April 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,5-7,11,15-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5-7,11,15-17 and 19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2008 has been entered.

Claims 1, 5-7, 11, 15-17 and 19 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

***Response to Declaration***

The declaration under 37 CFR 1.132 filed April 7, 2008 is insufficient to overcome fully any of the rejections of the claims set forth in the last Office action. The declaration comprises data comparing a freeze-dried and a spray-dried product, but it is limited to one particular embodiment. Therefore, this data is not commensurate with the scope of the instant claims. Clearly the data cannot be used to overcome embodiments falling within the scope of the claims that have been specifically in the art of record. Further, it is not clear that this result can be extrapolated past the embodiment requiring lutein and  $\gamma$ -cyclodextrin, and there is presently no claim limited to this embodiment.

***Claim Rejections - 35 USC § 102***

Claims 1, 5-7, 11, 15-17 and 19 are again rejected under 35 U.S.C. 102(b) as being anticipated by Mele et al (Carbohydr. Res., 2002), as set forth in the previous Office action.

Mele teaches the preparation of a complexes comprising lycopene with  $\alpha$ -cyclodextrin or  $\beta$ -cyclodextrin. The complexes are isolated by freeze-drying. See 1<sup>st</sup> paragraph under section 3 at page 1134. The reference is silent regarding the molar ratio of the complex that is formed. However, given the structure of carotenoids and how cyclodextrins form complexes in general, it would be expected that the cyclodextrin:carotenoid ratio would be about 1:1 or 2:1. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive. Applicant provides no other argument except to reiterate what was submitted in Dr. Madhavi's declaration. This declaration is addressed above. It is not sufficient to overcome the rejection. A finding of unexpected results for one obvious, but not specifically disclosed, product does not overcome an anticipation rejection.

Claims 1, 5, 11, 15 and 19 are again rejected under 35 U.S.C. 102(b) as being anticipated by Mele et al (Carbohydr. Res., 1998), as set forth above.

Mele teaches the preparation of a complex of  $\beta$ -carotene and  $\gamma$ -cyclodextrin that is isolated by freeze-drying. See 1<sup>st</sup> paragraph under section 2 at page 262. The reference is silent

Art Unit: 1623

regarding the molar ratio of the complex that is formed. As discussed above, it would be expected that the cyclodextrin:carotenoid ratio would be about 1:1 or 2:1, and the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive. Applicant provides no other argument except to reiterate what was submitted in Dr. Madhavi's declaration. This declaration is addressed above. It is not sufficient to overcome the rejection.

Claims 1, 6 and 7 are again rejected under 35 U.S.C. 102(b) as being anticipated by Pfitzner et al (BBA, 2000) as set forth in the previous Office action.

Pfitzner teaches the preparation of M $\beta$ CD complexes with  $\beta$ -carotene, lycopene, lutein and zeaxanthin. See section 2.2. The products are not isolated by freeze-drying. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) As above, the burden is on Applicant to demonstrate a novel or nonobvious difference.

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive. Applicant provides no other argument except to reiterate what was submitted in Dr.

Madhavi's declaration. This declaration is addressed above. It is not sufficient to overcome the rejection.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Szente et al (J. Incl. Phenom., 1998).

Sjente teaches the preparation of complexes comprising  $\beta$ -carotene and various cyclodextrins. See Table V. The products are prepared using suspension and coprecipitation techniques. The reference is silent regarding the actual method of isolation. As above, patentability is determined by the product itself, and the burden is on Applicant to demonstrate a novel or nonobvious difference. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) As above, the burden is on Applicant to demonstrate a novel or nonobvious difference.

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive. Applicant provides no other argument except to reiterate what was submitted in Dr. Madhavi's declaration. This declaration is addressed above. It is not sufficient to overcome the rejection.

***Claim Rejections - 35 USC § 103***

Claims 1, 5-7, 11 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mele et al (Carbohydr. Res., 2002).

Mele teaches as set forth above. The reference discusses the desirability of increasing the bioavailability of carotenoids, including lycopene,  $\beta$ -carotene, lutein and zeaxanthin, for their use in products such as drugs and cosmetics. One method for doing this is the encapsulation of the carotenoid in a cyclodextrin. See section 1. The reference does not exemplify complexes of all the carotenoids with a cyclodextrin.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare cyclodextrin ( $\alpha$  or  $\beta$ ) complexes with any of the carotenoids discussed by Mele in order to improve their bioavailability as taught in the reference. One of ordinary skill would be motivated to isolate them by freeze-drying because that is the method taught in the reference. In the absence of unexpected results, one of ordinary skill would reasonably expect success in preparing these compounds by this method because it is expressly suggested in the art.

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive. Applicant provides no other argument except to reiterate what was submitted in Dr. Madhavi's declaration. This declaration is addressed above. It is not sufficient to fully overcome the rejection. See discussion above.

Claims 1, 5-7, 11 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mele et al (Carbohydr. Res., 2002) in view of either of (1) Mele et al (Carbohydr. Res., 1998) or (2) Szente et al (J. Incl. Phenom., 1998).

Mele '02 teaches as set forth above. The reference does not teach the full range of recited cyclodextrins.

Mele '98 and Szente teach as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare complexes comprising any of the carotenoids discussed by Mele '02 with any cyclodextrin known to complex with a carotenoid, such as those taught by Mele '98 or Szente. One of ordinary skill in the art would be motivated to prepare these complexes in order to increase their bioavailability as taught by Mele '02. The artisan would reasonably expect success in isolating them by freeze drying because this method is also taught by this reference.

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive. Applicant provides no other argument except to reiterate what was submitted in Dr. Madhavi's declaration. This declaration is addressed above. It is not sufficient to fully overcome the rejection. See discussion above.

#### ***Allowable Subject Matter***

As discussed above, Applicant has submitted data demonstrating unexpected results for a freeze-dried product comprising lutein and  $\gamma$ -cyclodextrin. The current claims, limited to this embodiment, would be allowable.

Art Unit: 1623

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Leigh C. Maier/  
Primary Examiner, Art Unit 1623  
July 8, 2008